Richard B. Ashman
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December 12, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Docket No. 97N-484S

Dear Ms/Sir;

It has come to my understanding that the FDA is proposing to regulate bone allograft as a medical device. I totally disagree with the proposed regulation. Such regulation shows a complete lack of understanding as to how these tissues have been used for the last 100 years. Allograft tissue is commonly available in many forms to surgeons. The proposed regulation would place a new and disproportionate regulatory burden on companies that attempt to standardize the highly variable biological tissues. The message sent to the medical industry is, If you take the time and provide a more standardized material, you will be penalized.

The FDA should consider the high cost of the proposed regulations against the marginal gain in patient safety.

Sincerely,

Richard B. Ashman

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